

REMARKS

Applicant has received and carefully reviewed the Office Action of December 2, 2005. The Examiner vacated the Notice of Allowance dated December 22, 2004, and issued a new ground of rejection. The Examiner "finally" rejected claims 80-92, 101-103, 105-106, 107-116, 119, 122-124, 128-131, 133-136, and objected to the remaining claims as being dependent on a rejected base claim, but indicated that such claims would be allowable if rewritten in independent form, including all of the limitations of the intervening claims, in view of art cited by the Applicant in the IDS submitted March 21, 2005.

The Examiner made the instant Office Action Final, and cites 37 C.F.R. §1.97(c) and MPEP §609.04(b) as the basis for the finality of the Office Action. Applicant respectfully disagrees. Applicant filed the IDS on March 21, 2005, after the Examiner had issued a Notice of Allowance and prior to payment of the Issue Fee; therefore, Applicant submitted the IDS under 37 C.F.R. §1.97(d), not (c). As such, MPEP §609.04(b) does not allow for the Examiner to make the issuance of a new ground of rejection, final. Applicant respectfully requests that the Examiner make the December 2, 2005 Office Action non-final.

Claim rejections under 35 USC §102(b)

The Examiner rejected claims 80-84, 86-92, 10, 103, 105-106, 107-116, 122-124, 128-131, and 133-136 under 35 U.S.C. § 102(b), as being anticipated by DD 293,429 A5 to Tesch et al. (Tesch). According to the Examiner, Tesch

teaches an automated milking system which optically tests a milking parameter, and analyzes it in a stream in an analysis unit, communicates the result and automatically determines the fate of the sampled milk. The Examiner states that Tesch makes clear that any optically recognizable characteristics can be used, including light scatter, and that Tesch therefore anticipates the claims. Applicant respectfully traverses this rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Rejection of Independent Claim 80

Applicant acknowledges that Tesch generally teaches a method and apparatus wherein detectable changes (wahrnehmbare Veränderungen) in the milk are used to assess its quality and determine to which exit of the apparatus the milk should be directed. However, with regard to claim 80, Tesch does not anticipate claim 80, because the method taught in Tesch does not assess particles in the identified volume of milk by either a) counting of substantially individual somatic cells (step ii) a) of claim 80), or b) assessing at least one property of at least one biological particle in the volume of milk (step ii) b) of claim 80). The term "somatic cells" are not discussed anywhere in Tesch, neither explicitly, nor implicitly or inherently.

Furthermore, no counting of anything is taught in Tesch. In fact, Tesch does not describe any form of quantitative assessment of any particles in the sampled milk. In order to be able to count somatic cells in a milk sample, a person of ordinary skill in the art would recognize that under conditions described by Tesch, one would be required to distinguish between somatic cells and non-biological particles such as fat globules. Fat globules are ubiquitous in milk, and are of similar size and shape as somatic cells, but are present in numbers that are several orders of magnitude higher. As such, the teaching of Tesch cannot indicate or assess the number of somatic cells as stated in claim 80.

In addition, Applicant's claimed invention is not anticipated because the method of Tesch does not specifically assess biological particles as recited in step ii) b) of claim 80. Tesch does not teach discrimination of biological particles from any other type of particles, it merely describes detection of "wahrnembare Veränderungen" (translation "recognizable changes"), and mentions several possible causes of such changes, such as e.g. a "Verklumpung (lumps) or Schmutz (dirt)". Moreover, there is no ability to distinguish whether a "recognizable change" is due to a "Verklumpung" or to "Schmutz" in the method disclosed in Tesch.

Furthermore, Tesch teaches its method (page 4 lines 23-33 of the translation) as, "An optical sensor detects the optically recognizable characteristics of the udder secretion. These are packed in image form as information regarding the optical condition of the detection area and

carried on to an analysis unit wherein the area image is compared to the unchanged milk." Tesch teaches further that the differences in the characteristics of the milk sample are detected only when compared to normal milk. Further "...analysis of structure, texture, average grey scale value, and difference in grey scale values between adjacent image points" allows characteristics such as "lumps, flocks, clotted substances, dirt, blood, color changes and other optically recognizable changes..." to be detected, but not separately quantified. Applicant submits that the earliest filing date of Tesch is April 3, 1990. As such, the state of the art of analysis of particles in milk, at that time, would have been the same or similar to what Applicant discussed in his previous Declaration with respect to the Packard et al. reference, which was overcome in Applicant's previous Amendment and Response filed November 10, 2004.

The Examiner may recall that the Packard et al. reference was used as a reference to teach the most commonly used fluoro-opto-electronic method at the time, which is described under "Method C" in a publication by the International Dairy Federation: the International IDF Standard 148A:1995. Furthermore, in Applicant's previously submitted Declaration, under point 5, Applicant explained how an assessment of particles in milk is carried out when using the fluoro-opto-electronic method and what the characteristics of this method are, and contrasted that with the method of the present invention. Under point 7 of Applicant's Declaration, Applicant explained in detail why the fluoro-opto-electronic method could not be integrated into a process for a regulating a milking process. As such, Applicant's Declaration of November 10, 2004 is further

support that Tesch does not contain all the elements recited in claim 80 of the present application, and therefore Applicant requests withdrawal of the rejection.

Rejection of Independent Claim 107

For the same reasons as discussed above with regard to anticipation of claim 80, Applicant submits that the system of Tesch cannot anticipate claim 107, because the system of Tesch, as disclosed, does not comprise a means for assessment of particles in the identified volume by either: counting of substantially individual somatic cells (step ii) a) of claim 107), or assessing at least one property of at least one biological particle in the volume of milk (step ii) b) of claim 107).

The means for detecting "detectable changes" in Tesch does not count somatic cells. It also does not assess biological particles specifically, because it assesses any type of "recognizable change" without discriminating between the types of changes, e.g., lumps, dirt, etc.

Furthermore, the means in Tesch cannot count or quantify cells or assess biological particles. Thus, the apparatus disclosed in Tesch is not suitable for Applicant's claimed purpose, because it cannot detect differences between biological particles and other particles. Tesch does not contain all the elements recited in claim 107 of the present application, and therefore Tesch cannot anticipate Applicant's claimed invention. Therefore, Applicant respectfully requests withdrawal of the rejection.

Claim rejections under 35 USC §103(a)

Claims 85 and 109 were rejected under 35 U.S.C. §103(a) as obvious over Tesch, as applied to claims 80-84, 86-92, 102, 103, 105-116, 122-124, 128-131, 133-136 above in view of WO 99/41605 to Managan (Managan).

According to the Examiner, Tesch does not teach testing for fat content or sodium content in milk. Managan discloses automated milk analysis which uses measurement of fat and/or sodium content in a sample of milk to determine whether a milk sample has a sufficient quality. The measurements in Managan are performed on-line. In addition, sodium ion concentration, temperature, conductivity, butter-fat percentage, protein percentage and viscosity are also determined.

The Examiner states that it would have been *prima facie* obvious for one of ordinary skill in the art, at the time the invention was made, to include measurements of fat and sodium in the automated analysis machine of Tesch. Further, one of ordinary skill would have been motivated to do so because Managan teaches that these parameters are directly related to the presence of mastitis and poor milk quality. Applicant respectfully traverses this rejection.

Managan is a PCT application that was filed on February 12, 1999, and published on August 19, 1999. As such, Managan is available as prior art under §102(a) and §102(b) only as of the publication date of the application. Applicant's earliest priority date is based on a Danish national patent application filed November 5, 1998.

Therefore, Managan is not prior art to the instant application, and cannot be the basis of a rejection under 35 U.S.C. §103(a). Applicant respectfully requests withdrawal of this rejection.

The Examiner rejected claims 101 and 119 under 35 U.S.C. §103(a) as being unpatentable as obvious over Tesch, as applied to claims 80-84, 86-92, 102, 103, 105-116, 122-124, 128-131, 133-136, in view of Tsenkova et al., 1994 (PTO 1449 - AS) filed November 2003 (Tsenkova). **(Note: Applicant believes that the Examiner cited Managan in the first sentence of this rejection in error, as Tsenkova, and not Managan, is cited again within the remainder of the rejection)** According to the Examiner, Tesch does not teach testing of spectrophotometric properties. Tsenkova, however, allegedly teaches methods of measuring milk quality by near infrared irradiation (NIR) of milk samples. The samples were subjected to NIR transmittance experiments and the results correlated with high somatic cell count and the presence of mastitis.

The Examiner states that it would have been *prima facie* obvious for one of ordinary skill in the art, at the time the invention was made, to include spectrophotometric property measurements in the automated analysis machine of Tesch. Further, one of ordinary skill would have been motivated to do so because Tsenkova teaches that these parameters are directly related to the presence of mastitis and poor milk quality. Applicant respectfully traverses this rejection.

As stated above, Tesch teaches that the differences in the characteristics of the milk sample are detected only when compared to normal milk. Further "...analysis of structure, texture, average grey scale value, and difference in grey scale values between adjacent image points" allows characteristics such as "lumps, flocks, clotted substances, dirt, blood, color changes and other optically recognizable changes..." to be detected, but not separately quantified. In other words, Tesch utilizes a simple optical transmission sensor which detects objects in the flow path. There is no teaching in Tesch about spectral analysis, especially in any infrared wavelengths. The method of Tesch sorts dirty milk from pure milk in a very rough manner, based on information concerning optical properties of the milk, such texture and color.

Tsenkova, on the other hand, teaches that NIR spectral analysis of individual milk samples could be used to detect mastitis in cows. Tsenkova only shows that testing of individual samples of milk from a bucket using a quartz cuvette. The method of Tsenkova is not a real-time on-line analysis of milk samples (page 2, paragraph under "Milk Samples and Spectra"). The tests in Tsenkova can only compare different milk samples from the same cow as the spectra derived from each cow is different (page 2, last paragraph under "Data Treatment"). The method of Tsenkova cannot analyze individual somatic cells or count cells. Tsenkova merely correlates the collective transmittance of a milk sample at a certain wavelength with overall collective (not individual) somatic cell count, and only on a per individual cow basis. Furthermore, there is no teaching in

Tsenkova how one would apply the method of Tsenkova to the apparatus of Tesch to make the process automated.

The combination of Tesch with Tsenkova does not teach or suggest the counting of individual somatic cells in an on-line milk sample nor does it assess a biological particle as claimed in claims 101 and 119. Applicant submits that the Examiner cannot maintain a *prima facie* obviousness rejection under 35 U.S.C. §103(a) because the prior art references of Tesch and Tsenkova, when combined, do not teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in Applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Neither reference teaches or suggests how to adapt the optical image method of Tesch for analyzing particles in the milk as the milk is flowing from the milking apparatus, i.e. in real-time as claimed in the present invention, with the individual sample NIR spectral analysis of Tsenkova. Thus, the combination of references does not teach each and every limitation of the claimed invention. While it may be obvious to try to combine the two teachings, to arrive at the present invention, the combination of Tesch and Tsenkova does not teach all the claim elements, and the Examiner has not provided a reasoned basis of how one of skill in the art would combine the two teachings with a reasonable expectation of success.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that

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they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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